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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,676

10/31/2003

Martin T. Gerber

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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,676	<b>Applicant(s)</b> GERBER ET AL.	
	<b>Examiner</b> MATTHEW J. KASZTEJNA	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-36 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-36 and 38-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2008 has been entered.

### ***Notice of Amendment***

In response to the amendment filed on December 3, 2008, amended claims 27 and 36 are acknowledged. The following new and reiterated grounds of rejection are set forth:

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-24 of copending Application No. 10/698,213. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims involve an obvious broadening of the claims in application serial no. 10/698,676.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-32, 36 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,599,294 to Edwards et al. in view of U.S. Patent No. 5,486,161 to Lax et al. in view of U.S. Patent No. 6,231,591 to Desai

**In regards to claims 27 and 36**, Edwards et al. disclose a system for delivering a denervating agent to a prostate gland comprising: an imaging apparatus 42 sized for insertion into a rectum of a patient to generate one or more images of a prostate gland (see Col. 6, Lines 65-67), the imaging apparatus having a longitudinal axis and formed with a hole 40 (see Figs. 3-4), a handle 158, and a wheel 170 fixed to the shaft and

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rotatably connected to the handle to permit rotation of the shaft relative to the handle and about the longitudinal axis while the shaft is inserted into the rectum (see Fig. 13 and Col. 10, Lines 60-63); a needle 36 for insertion through the hole of the shaft based and into a rectal wall of the patient in proximity to the prostate gland based on the one or more images connected to a first actuator 166 (see Figs. 5-9), the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen, wherein the needle extends out of the shaft (see Col. 5, Lines 20-30). Edwards et al. teach of tab 166 connected to stylet 62, responsible for advancing the stylet into a target tissue as the tab is moved forward (see Col. 10, Lines 58-63) but are silent with respect to a spring-loaded needle and wherein actuating a spring mechanism to cause the distal end of the needle to be inserted into the prostate gland. Lax et al. teach of an analogous medical probe having a cutting cannula 84 which is spring-loaded in a retracted position and wherein a release tab 108 is pushed down to move the cannula forward when desired. It would have been obvious to one skilled in the art at the time the invention was made to include a spring-loaded needle in the apparatus of Edwards et al. to allow for more efficient and effective actuation of the needle into tissue as taught by Lax et al.

**In further regards to claims 27 and 36**, Edwards et al. teach that rotation of the torque and thrust rod 130 about its central axis will cause a corresponding rotation of the stylet guide housing and deflection of the stylet in directions outside of the axial plane. This combined with axial movement of the catheter to an optimum position in a duct and rotation of the catheter about its central axis yields an infinite variety of stylet

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orientation angles. A combination of these movements provides greater choices of stylet angles so that the stylet can be advanced into target tissue at any angle from the catheter (see Col. 8, Lines 25-38). Furthermore, as a hollow tube, it can be used to deliver a treatment fluid such as a liquid to a target tissue. The liquid can be a simple solution or a suspension of solids, for example, colloidal particles, in a liquid. Since the stylet is very thin, it can be directed from the catheter through intervening normal tissue with a minimum of trauma to the normal tissue. However, Edwards et al. are silent with respect to a method of inserting the needle at a first target location and delivering a denervating agent, then moving to multiple locations thereafter and repeating the procedures. Desai teaches of an analogous system for delivering a denervating agent to a prostate gland comprising: an imaging apparatus 302 sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole; a needle positioned through the hole of the imaging apparatus for insertion through a rectal wall of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen, wherein the needle is capable of extending out of the imaging apparatus parallel the long axis of the imaging apparatus (see Col. 19, Line 67 - Col. 20, Line 11 and Fig. 25).

Furthermore, Desai discloses a method of localized fluid therapy (see Fig. 28 and Col. 19, line 57 – Col. 20, Line 51). In particular, the probe 309 and needle (FIG. 25) are inserted into the patient's body (block 406, FIG. 28) through an appropriate opening, such as an incision, or through a natural passageway such as a urethra or cervical

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canal, etc. The needle 306 is used to apply fluid to a tissue surface, or is advanced into body tissue in need of treatment (block 410), the needle depth being observed by use of any of various imaging means, such as those listed including an endoscope, a scale on the injector 348 or probe handle, or noninvasive imaging and position detection using X-RAY, CT scan, fluoroscopy, ultrasound etc. Treatment fluid is then injected (block 412) into the specific target area of tissue without affecting the surrounding area. The needle is then removed from the treatment site (block 414). And thus, **in regard to claims 31-32**, the apparatus can be either removed, or a new site in need of treatment can be identified and therapy applied and thus theoretically as many treatments may be carried out as desired. It would have been obvious to one skilled in the art at the time the invention was made to inject a denervating agent at a variety of target sites within the body using the apparatus of Edwards et al. to more effectively treat diseased tissue as taught by Desai.

**In regards to claims 28-29 and 45**, Edwards et al. discloses a system for delivering a denervating agent to a prostate gland, wherein the imaging apparatus comprises an ultrasonic imaging apparatus (see Col. 6, Lines 65-67).

**In regards to claim 30**, Edwards et al. discloses a system wherein the imaging apparatus is operably connected to a handle (see Fig. 3) and wherein rotating the shaft further comprises rotation the shaft relative to the handle (see Fig. 13 and Col. 8, Lines 25-39 and Col. 10, Lines 60-63).

Claims 33, 35 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,599,294 to Edwards et al. in view of U.S. Patent No. 5,486,161

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to Lax et al. in further view of U.S. Patent No. 6,231,591 to Desai in further view of U.S. Patent No. 6,365,164 to Schmidt.

**In regards to claims 33, 35 and 44**, Edwards et al., Desai and Lax et al. disclose a system for delivering a denervating agent to a prostate gland but are silent with respect to the denervating agent including botulinum toxin. Schmidt teaches methods for treating neuronally-mediated urologic and related disorders and more particularly, benign prostatic hyperplasia (BPH), by administering a composition that includes at least one neurotoxic compound. Such a neurotoxin can be botulinum toxin type A (see Col. 4, Lines 3-29). It would have been obvious to one skilled in the art at the time the invention was made to use a composition including botulinum toxin type A with the device of Edwards et al., Desai and Lax et al. in order to help more effectively treat BPH as taught by Schmidt.

Claims 27-32, 34, 36, 38-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,486,161 to Lax et al. in further view of U.S. Patent No. 5,599,294 to Edwards et al.

**In regards to claims 27, 30-32, 34, 36, 41**, Desai discloses a system for delivering a denervating agent to a prostate gland comprising: an imaging apparatus 302 sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole; a needle positioned through the hole of the imaging apparatus for insertion through a rectal wall of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the

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lumen, wherein the needle is capable of extending out of the imaging apparatus parallel the long axis of the imaging apparatus (see Col. 19, Line 67 - Col. 20, Line 11 and Fig. 25). Furthermore, Desai discloses a method of localized fluid therapy (see Col. 19, line 57 – Col. 20, Line 51). Desai disclose an apparatus wherein a slidable portion 338 is responsible for extending and retracting a needle 306 into tissue but is silent with respect to a spring-loaded needle and wherein actuating a spring mechanism to cause the distal end of the needle to be inserted into the prostate gland. Lax et al. teach of an analogous medical probe having a cutting cannula 84 which is spring-loaded in a retracted position and wherein a release tab 108 is pushed down to move the cannula forward when desired. It would have been obvious to one skilled in the art at the time the invention was made to include a spring-loaded needle in the apparatus of Desai to allow for more efficient and effective actuation of the needle into tissue as taught by Lax et al. Desai and Lax et al. are silent with a wheel used to rotate the orientation of the needle. Edwards et al. teach of an analogous apparatus wherein rotary dial 170 is attached to the catheter 154 and can be used to rotate the catheter for orientation of the stylet or stylet (see Fig. 13 and Col. 10, Lines 58-64). Edwards et al. teach that rotation of the torque and thrust rod 130 about its central axis will cause a corresponding rotation of the stylet guide housing and deflection of the stylet in directions outside of the axial plane. This combined with axial movement of the catheter to an optimum position in a duct and rotation of the catheter about its central axis yields an infinite variety of stylet orientation angles (see Col. 8, Lines 25-38). Thus, it would have been obvious to one skilled in the art at the time the invention was made to allow for rotary

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movement of the shaft with respect to the handle in the apparatus of Desai and Lax et al. to provide a user greater choices of stylet angles so that the stylet can be advanced into target tissue at any angle from the catheter as taught by Edwards et al.

**In regards to claims 28-29 and 45,** Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the imaging apparatus comprises an ultrasonic imaging apparatus (see Col. 19, Lines 64-67).

**In regards to claim 38,** Desai discloses a system for delivering a denervating agent to a prostate gland, further comprising a denervating agent delivery 348 assembly coupled to the needle to deliver the denervating agent through the lumen (see Col. 17, Lines 18-57).

**In regards to claims 39-40,** Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery system assembly 348 includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen. As can be seen in Fig. 25 the second actuator comprises a plunger as well as a hub and a fluid line for attachment of the reservoir to the needle (see Col. 17, Lines 53-55).

**In regards to claims 42-43,** Desai discloses a system for delivering a denervating agent to a prostate gland, wherein the denervating agent delivery assembly 348 includes a first reservoir to hold a substantial amount of the denervating agent, a second reservoir to hold a discrete dose of the denervating agent, and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein the second reservoir refills with another discrete dose of the denervating agent

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from the first reservoir following actuation of the second actuator (see col. 20, Lines 51-65, and Col. 21, Lines 18-30). Syringe 348 is interpreted to be the first reservoir and the lumen of needle 306 is interpreted to be the second reservoir.

### ***Response to Arguments***

Applicant's arguments with respect to claims 27-36 and 38-45 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./  
Examiner, Art Unit 3739

/Linda C Dvorak/  
Supervisory Patent Examiner, Art  
Unit 3739

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